# EXHIBIT 24

# Expert Report Re Digitek® and its Post-Marketing Safety Surveillance

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**10 Dec 2010**

## Background

I have been asked to review the adverse event reports (AERs) for Digitek® during the period prior to its recall on April 25, 2008 to determine whether these AERs or any other data reveal any signal or indication that defective Digitek® tablets, including but not limited to double thick tablets, might have been on the market during that time. To facilitate my work, I was provided a great many documents; my requests for additional specific documents were quickly honored[1].

The US Food and Drug Administration (FDA) has developed an extensive and expensive process for the licensing of drugs for interstate commerce. This process requires that new pharmaceutical products be demonstrably both safe and effective under a meticulously controlled and highly standardized series of studies that progress to and include rigorous clinical trials. Reporting to the FDA and inspections by the FDA are standard parts of this process. At a minimum, getting a marketing authorization from the FDA involves several years, many millions of dollars, and the careful monitoring of a few thousand patients. Marketing authorization holders of drugs already approved are subject to similar rigorous ongoing regulation and inspection.

The words 'safe and effective' in the previous paragraph are relative terms, not absolutes. Whether a drug or a vaccine is ultimately judged to be both safe and effective by the FDA depends on many intangibles that include but are not limited to the indication (i.e., why the drug is needed by any given patient), the use context and the current state of the art *vis-à-vis* alternative drugs, their relative safety and effectiveness in actual use, and the consequences of doing nothing[2]. Essentially, this is a risk-benefit calculation using all available relevant information.

## Pharmacovigilance

Pharmacovigilance may be defined as the science of collecting, monitoring, researching, assessing and evaluating data, including but not limited to AERs, for the purpose of helping to identify new information about hazards associated with medicines and to help prevent harm to patients. The etymological roots are: *pharmakon* (Greek), "drug;" and *vigilare* (Latin), "to keep awake or alert, to keep watch."

Experience has taught that the following four statements are unqualifiedly true:

- No drug works in everyone
- No drug is without side effects
- No drug is indicated for everyone
- All drugs are contraindicated for some people

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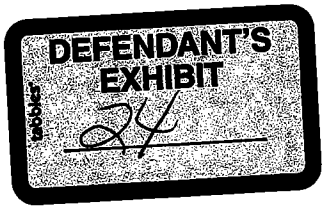
[1] See Attachment A

[2] As a hypothetical example, a drug that causes fatal cardiac arrest in 5 % of patients but puts cancer into remission in 80 % might well be considered 'safe' if the indication is a rapidly fatal cancer that kills 90 % of patients in a very short period of time.



New drugs are now often subjected to FDA-dictated special studies or other forms of intensive active adverse event surveillance during the first few years of marketing. And these requirements are increasingly being mandated in addition to the normal and customary spontaneous reporting requirements that are standard once a drug is licensed and marketed.

Pharmaceutical companies have long received communications[3] from the learned intermediaries (i.e., physicians mostly) who prescribe their licensed pharmaceutical products, as well as from other health care professionals, patients and their relatives, lawyers and the constantly evolving medical literature, etc. The subject of many of these communications is the reporting of adverse events (AEs) that have occurred in temporal relationship to drug use. And the stimulus for reporting, though variable and sometimes opportunistically pecuniary, is most often a simple suspicion that the reported adverse event was caused by or may have been caused by one or more of the drugs being taken. It is important to note that AEs reported to the manufacturer are recorded in the exact terminology of the reporter, and there is no effort to verify nor to challenge their accuracy. Nonetheless, the FDA often recodes (changes) the AEs reported to it when entering them into the FDA's Adverse Event Reporting System (AERS) data base. Also importantly, it must be explicitly stated that the AEs that are reported do not imply a direct cause-effect relationship for the product and the reported event(s).

Most, if not all, ethical pharmaceutical companies have continuously and contemporaneously recorded received AE reports into a cumulative referential database of their own design, and have continuously updated and maintained this at their own cost, even before the FDA required, as it now does, that manufacturers forward such reports to them. Additionally, depending on the seriousness and expectedness of each individual AE report, the FDA mandates a rigid schedule for reporting with penalties for being late.

In what has evolved into a dense regulatory thicket, depending on the seriousness and expectedness of the event, the company must then report these to the FDA, with the most serious requiring immediate notification. Companies that fail to report in a timely manner are subject to being fined by the FDA. Post-marketing safety surveillance is now a highly technical enterprise that includes sophisticated data mining techniques in an ongoing search for signals, evidence of possible cause and effect in newly prominent drug-event pairs. Cause and effect must ultimately be determined by additional studies/investigations.

A simple rationale can be constructed to help understand the potential utility of AERs in promoting drug safety:

- At the point in time when a new drug is licensed by the FDA, the cumulative human experience for documenting both safety and effectiveness is relatively small: usually a total of only a few thousand people have been exposed to the drug in question
- Almost all of these people have been especially selected/recruited, and almost all of the gleaned experience has been acquired in the aforementioned rigorously controlled clinical trials. Every drug being tested has been given at the right time in the right dose via the right route, according to an FDA approved written protocol

[3] In various formats including letters, phone calls, verbal reports to company representatives, etc.

- However, when the drug is marketed, it is not unusual for hundreds of thousands or even several million people to be exposed to that drug during its first year of use, but the circumstances are now very different from the previously described controlled clinical trial arena:
  - People for whom the drug is contraindicated do take the drug anyway
  - Off label use (i.e., using the drug to treat a different disease from what the FDA approved) can be quite common[4]
  - And it gets taken in an incorrect dose, or via an incorrect route, etc. (too much, too little, too often, etc.)
  - If a given drug actually causes a bad event, but does so only one time in 100,000 exposures or even once in a million exposures (such as is now known to have happened in the 1970's with so-called swine flu vaccine of the day causing Guillian-Barré syndrome), such a reaction will remain unseen in clinical trials and will only become apparent after millions of exposures during normal use
  - Drug interactions that were deliberately minimized in clinical trials can now develop, presenting as new medical problems or a worsening of existing problems. Such interactions become possible with any of the whole pharmacopoeia of marketed prescription and OTC drugs that are used concomitantly

So, the true safety profile of a new drug can only be approximated but cannot be confidently established until after the drug is on the market, after it is used by very large numbers of people, and then only upon competent analysis of the reported adverse events[5]. This is the science of pharmacovigilance in actual practice.

As if it weren't already complex enough, this situation is made even more complex by the large and growing number of reports that must be regularly analyzed on a recurrent basis. The FDA's AERS database now contains more than 4,000,000 reports, each involving one or more drugs with one or more adverse event preferred terms (PTs):

- More than 300,000 new reports are being added each year
- Greater than 9,000 unique event codes (MedDRA[6] PTs) exist in the database
- Greater than 7,000 drug and biologic trade names exist
- Greater than 3,000 drug generic names (generic plus combination drugs) have been reported from health professionals, suspect only
- Greater than 63,000,000 distinct and unique drug-event pairs are possible

A similar, albeit smaller, system has been set up for vaccines, called the Vaccine Adverse Event Reporting System (VAERS).

**The Very Special Case of Digoxin**

[4] Any licensed physician can prescribe any licensed drug or vaccine without regard to the FDA-approved indication(s), though a bad outcome under such circumstances may well invite legal remedy on behalf of a patient who is allegedly so injured

[5] A very well-written article sheds some good light: Expecting the Unexpected — Drug Safety, Pharmacovigilance, and the Prepared Mind, byAnne Trontell, New England Journal of Medicine, 351;14 September 30, 2004

[6] MedDRA: the Medical Dictionary for Regulatory Activities, updated internationally twice each year

In the late 1700's, news of the spectacular success of a particular English folk remedy against the dreaded disease called 'dropsy' caused a sensation. In 1785 William Withering, a physician and botanist, published *An Account of the Foxglove and its Medical Uses, With Practical Remarks on the Dropsy, and Some Other Diseases*, the results of his scientific experiences using the powdered dry leaves of a plant common to many English gardens, Digitalis purpurea – the purple foxglove. Its effect was almost magical in many cases of dropsy, a condition we now call congestive heart failure (CHF).

CHF can result from many different diseases, but in simple lay terms, CHF results when the physical demands on the heart can no longer be met, because one or more underlying diseases has weakened (damaged) the heart. The heart (a muscular organ) is a pump, moving blood around in the body, getting rid of metabolic waste in the kidneys, getting rid of carbon dioxide and acquiring fresh oxygen in the lungs, etc. Diseases such as chronic hypertension, aortic or mitral valvular disease, loss of heart muscle from myocardial infarction, etc., can injure and weaken the heart. A damaged heart tends to speed up, trying to keep up with circulatory demand, but this actually decreases its efficiency as a pump, so it falls further and further behind the harder it works to meet the body's needs. The effect on the kidney can be dramatic, as fluid normally excreted as urine fails to be completely excreted and, instead, builds up in the body's tissue spaces, especially the lungs and lower extremities where it accumulates, marked by great swelling. This is classic dropsy, a swollen uncomfortable state with a rapid heart beat and overwhelming fatigue. After some weeks or a few months, if not successfully treated and the underlying cause or causes effectively addressed, the racing heart reaches its biological limit, giving up, yielding to inevitable premature death.

The administration of a decoction from those dry powdered leaves had an immediate and salutary effect in many dropsy cases. Within an hour or two, the heart slowed but with a stronger, more forceful beat. Blood circulation was immediately improved and, over the next few days, the kidneys started to get rid of that burdensome accumulated fluid. In many instances, patients perceived to be on their death bed simply got up and experienced the restoration of something approaching normal life. This could often last for many years.

We now know that those powdered leaves contain a certain chemical, a powerful drug, the first of the cardiac glycosides. We call this drug digoxin. It is the active ingredient in Digitek®. Digoxin has added many years to the individual lives of a great many millions of people. And, though medicine has certainly advanced and there are many newer drugs for CHF and its complications, hundreds of thousands of Americans continue to take digoxin every day, prescribed by their physicians on an individual basis because the latter continue to find that its unprecedented sometimes spectacular benefits far outweigh the risks of using digoxin.

We long ago standardized the drug and no longer use powdered leaves. The purified drug mixed with inert ingredients is available in tablet form, in two strengths: 0.125 mg and 0.250 mg.

Digoxin is one of the oldest drugs in the US Pharmacopoeia. It is also one of the drugs regarded by the FDA as having a narrow range between an effective dose and a possibly toxic dose. But, just as I have been careful to define the words 'safe and effective' in a regulatory context, I need to address digoxin toxicity as it occurs in clinical use. We now have a laboratory test that is routinely available to physicians to determine the actual blood level of digoxin in their patients.

Ongoing monitoring of digoxin level helps physicians to manage their patients, similar to the way that the insulin needs of diabetics are monitored. But digoxin toxicity is most often a mild, even subtle event, usually not a catastrophic event with dire implications. Indeed, when I was trained in internal medicine and before the blood test was available, one of the preferred and time-honored methods for cardiologists to "digitize' their patients was to rapidly increase the early doses up to the point where the patient developed the first signs and/or symptoms of toxicity. The physician would then back off a bit, having thus quickly achieved maximum therapeutic efficacy.

It is important to note that people who use digoxin are commonly ill, often quite ill, with one or more serious, possibly life-threatening, underlying chronic disease processes, resulting in the CHF that is the primary indication for digoxin. As a group, such patients frequently experience high rates of hospitalization and mortality from their underlying and ongoing disease processes. According to the latest update (2010) of relevant data on the American Heart Association website, heart failure now affects an estimated 5.8 million Americans, adults 20 or older. The one year mortality rate is high, with one in 5 dying. Fifty-nine percent of men and 45% of women die within 5 years of diagnosis[7].

Managing patients on digoxin is both an art and a science. There are patients who show evidence of toxicity despite blood levels well within the normal therapeutic range. Also, some patients with very high blood levels (far in excess of the normal range) show no evidence of toxicity. Despite these difficulties and variabilities, many, many Americans are successfully treated with digoxin every day.

**My Background and Training**

I was trained in epidemiology and then served as a career staff epidemiologist with the US Centers for Disease Control and Prevention (CDC) for 25 years, after having completed medical school with post-graduate specialty training in internal medicine and infectious diseases. After retiring from the federal government I worked as an epidemiologist for two major pharmaceutical manufacturers. I was in charge of monitoring the safety profile of all Merck vaccines globally for 5 years, and then spent 3 years in charge of post-marketing safety surveillance for about a quarter of all drugs marketed globally by Johnson and Johnson and its subsidiaries. The ongoing and complex analysis of a regular flow of adverse event reports and the communication of my findings and recommendations to senior management in language they could understand was my instructive daily fare for these 8 years.

**My Opinion**

From the post-marketing safety surveillance perspective, digoxin is a mature drug. Under normal conditions, absent the glare and stimulus of publicity, it would be expected to generate a slow trickle of adverse event reports, tiny in number despite a high, even very high, level of exposure. And this is exactly the case.

Table 1 shows all adverse events reported to Digitek®'s manufacturer during the period 2000 through 2008, up to but not including the recall: 98 total reports during 9 years. Such a small number of AERs could seem surprising, given the huge number of people exposed to digoxin

[7] http://americanheart.org/downloadable/heart/1265665152970DS-3241%20HeartStrokeUpdate_2010.pdf

each day, and the fact that the FDA receives about 1,000 AERs for all drugs each working day. Correctly interpreting the reported adverse events requires experience and some considerable maturity; as such data are quite susceptible to misinterpretation or to being misconstrued in many different ways.

**Table 1. Number of Digitek® Expedited and Periodic AE Reports (MedWatch), by Year of Manufacturer Receipt**

| Year | Expedited | Periodic |
|---|---|---|
| 2000 | 2 | 7 |
| 2001 | 1 | 8 |
| 2002 | 0 | 8 |
| 2003 | 3 | 13 |
| 2004 | 1 | 11 |
| 2005 | 0 | 8 |
| 2006 | 5 | 12 |
| 2007 | 2 | 10 |
| 2008 | 5 | 2 |
| **TOTAL** (n = 98) | **19** | **79** |

The first and only report of "a double thick" Digitek® tablet was made by a retail pharmacist on July 9, 2004. This was a product complaint regarding a single tablet; no associated adverse event was reported. Indeed, in a report made as a result of a December 1, 2004 inspection, the FDA inspector noted that "no additional complaints or reports of thick tablets have been received for this high volume product" (page 6). And she also noted as to batches manufactured in 2003-2004 that there were no trends observed in regard to complaints (page 9). In the more than 6 years that elapsed since July 2004, up to the writing of this expert report, in late 2010, no other reports of double thick tablets have occurred.

In November 2007, during the manufacturing process, 5 apparently double-thick tablets, all from batch 70924A, were discovered during packaging, as described on page 7 of this report in the health hazard evaluation (HHE) discussion. An additional 15 double thick tablets were discovered in unpackaging in January 2008. These were also from batch 70924A. Thus, the manufacturer is aware of a total of 21 such tablets, none of which reached a consumer.

Significantly, none of the total of 98 adverse event reports associated with Digitek since the year 2000 (these AERs are summarized in Table 1 and detailed in Appendices B and C of the present document) mentions or includes the term "double thick" or any similar product description. Indeed, the only mention I could find of a physically changed product referred to "… tablets that appeared as though they were disintegrating…" (MedWatch report number 2008AL001819).

The period from 2000 up to and including 2003 establishes Digitek's reporting baseline: a steady trickle of AEs (n = 42 for the 4-year period) that points randomly in no particular direction (See Attachment B for the line listing of these AEs).

The period 2004 through 2008 (where n = 56), when the first report was received of a double thick tablet up to the recall, fails to demonstrate any observable or meaningful change from the established pattern (See Attachment C for the line listing of these AEs).

In the 4-year baseline period 2000 through 2003 there are 11 reports[8] that include variations on the theme of "lack of effect, low blood digoxin level, tachycardia, under dose". In that same period there was only one report[9] on the theme of "toxicity, overdose, high blood level, bradycardia". These data may then be meaningfully compared with reports received during the period 2004-2008 when the 21 double thick tablets referred to above were observed. There are 7 reports that are variations on the theme of lack of effect[10], while 5 reports include variations on the theme of toxicity[11]. Table 2 summarizes these results.

**Table 2. Summary: Number of Reports of Lack of Effect and Toxicity Received During the Periods 2000-2003 and 2004-2008**

| AE Reports by Period | Period 2000-2003 | Period 2004-2008 |
|---|---|---|
| **All Reports This Period** (n = 98) | 42 | 56 |
| **"Lack of Effect" Subset** | 11 | 7 |
| **"Toxicity" Subset** | 1 | 5 |
| **SUBSET TOTALS** | **12** | **12** |

Returning to Table 1, attention is drawn to the column marked "Expedited". If a significant number of people were to have been either harmed by over dose (i.e., toxicity) or harmed by under dose (i.e., lack of effect) during the period 2004 through 2008 because they had consumed double-thick tablets with up to twice the labeled drug content or with less than the specified amount of active ingredient, it would show up in this column.

A careful review of the cases reported during this period shows no evidence of change for over dose nor for under dose. **The pattern established before 2004 is the same as the pattern during the 2004-2008 period**. I see no variation or modification of pattern, no clustering, nothing at all to indicate any change in the established reporting of AEs for this drug.

In early 2008 Actavis contracted with Jerrold Leikin, MD, Director of Medical Toxicology ENH OMEGA, to perform a health hazard evaluation (HHE). The stimulus was the product recall that followed the discovery, as described previously, of 5 digoxin 0.125 mg tablets "with a thickness approximately double to that required", found during packaging/filling operations of batch 70924A on packaging line #405 in November 2007, plus 15 more tablets from the same batch discovered during unpackaging. Dr. Leikin's report, dated April 18, 2008, states that during the period January 1, 2005 until March 31, 2008, "an internal review of domestic spontaneously reported adverse events" noted "11 adverse events"[12]. To facilitate comparison and understanding, I have placed these AE reports in tabular array identical to Table 1 above. Table 3 below contains these data.

[8] MedWatch report numbers C00-029, C00-030, C00-031, C00-036, C01-011, C02-004, C03-003, C03-013, C03-015, C03-022 and C03-037.
[9] MedWatch report number C03-028.
[10] MedWatch report numbers C04-060, C06-009, C06-030, 2006AL001204, 2007AL000909, 2008AL001819 and 2008AL001820.
[11] MedWatch report numbers C04-004, 2006AL000994, 2006AL003564, 2008AL000378 and 2008AL001710.
[12] This should be 11 AE reports, since 25 distinct AEs are listed in the report

**Table 3. AE Reports Discussed in the Health Hazard Evaluation of April 18, 2008 Covering the Period January 1, 2005 through March 31, 2008**

| Year | Expedited | Periodic |
|---|---|---|
| 2005 | 0 | 0 |
| 2006 | 2 | 4 |
| 2007 | 0 | 3 |
| 2008 | 0 | 2 |
| **TOTAL** (n = 11) | **2** | **9** |

The report states "…a pattern of events were (sic) not identified for this product related or unrelated to known adverse events…". I agree with this interpretation of the data.

In the plethora of documents supplied to me, I was able to find AER data for a much longer period, i.e., since 2000, as shown in Table 1. After examining all of the reports and documents supplied to me by the law firm of Messrs Tucker, Ellis and West, I have seen nothing that could even be remotely indicative of patient harm from 'double thick tablets' of digoxin. Instead, I see a constant pattern of AEs that do not cluster nor point towards nor offer any hints at harm from an over dose or an under dose or anything else at all notable in any way. Trickling in at a fairly constant rate of less than one per month for the entire 9 year period, the total number of reports is simply too small to hide or to obscure any epidemic of harm from either double thick or variable dose tablets, or any change at all in the established pattern of spontaneous reporting for this product.

**These data strongly and consistently** – even remarkably, given the huge number of individuals who have used this drug during the last decade - **support instead the absence of demonstrable harm**. If the drug actually did result in harm of any kind, including interacting with previously non-existent new drugs, there would have been a pattern change, a number change, something different, something immediately apparent, something new.

Conspicuously, there is nothing different.

Additionally, one can be sure that the FDA, having learned of the possible existence of double thick Digitek tablets on the market, would leave no stone unturned in its search for any evidence of possible harm to the consumer. The final question then arises whether any of the AEs that may have been notified directly to the FDA, thus bypassing the manufacturer, are qualitatively or quantitatively different from the subset of those reported and made known to the manufacturer. The FDA's apparent answer is 'No', based on the following statement specifically concerning the Digitek recall, extracted from an official FDA online publication[13]:

> "…**In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely**…"

[13] http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm

**My Conclusion**

Despite an exhaustive review of a very large number of relevant documents, no evidence of any harm of any kind to persons exposed to Digitek® was discovered or demonstrated in this review.

Aside from the solitary retail pharmacist report of a double thick tablet on July 9, 2004, a tablet that was not consumed, I discern no safety signal nor evidence of any kind that any possibly defectively manufactured Digitek® actually reached the market.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10 December 2010

ATTACHMENT A

**DOCUMENT INDEX**

| |
|---|
| **Process Validation & Prior Approval Supplement Documents** |
| 0.25 mg Process Validation |
| 0.125 mg Process Validation |
| 0.5 mg Process Validation |
| PAS dated 6/12/02 |
| **Batch Records, Finished Product, and Stability Testing; SOPs** |
| Full Batch records for: 70207, 70770, 70836 and 70925, 80226, 80228, and 70148 |
| Batch Record 70924A; Reconstituted Bitler Report |
| Finished product forms for batches: 60777, 60994, 60371, 70025, 70454, 70559, 70836, 80002 and 80202 |
| Stability Studies – Recalled batches: 60319, 70023, 70078, 70081, 70174, 70670, 80133, 71049; 71050, 71051 & finished product test report. |
| Various SOPs |
| **Documents Relating to Plaintiff's Potential Deposition** |
| Deposition Questions with document tabs 6, 7, 8, 9, 10 & 11. |
| **FDA Recall Documents** |
| Digitek Recall Notice 4/25/08 |
| Mylan E-mail regarding double thick tablet |
| **FDA General Documents** |
| ANDA |
| 1995 FDA Letters |
| FDA "Facts & Myths About Generic Drugs" |
| Warning letter dated 1/09/07 |
| Warning letter dated 8/15/06 |
| Warning letters dated 2/01/07 and 2/02/07 |
| 483 dated 2/08/06 |
| 483 dated 8/10/06 |
| 483 dated 5/20/08 |
| 12/01/04 Inspection Report |
| 484 Sampling for: 377410 |
| 484 Sampling for: 448881 |
| 484 Sampling for: 448892 |
| 484 Sampling for: 453913 |
| 484 Sampling for: 454866 |
| 484 Sampling for: 462746 |
| 484 Sampling for: 462753 |
| 484 Sampling for: 157503 |
| 484 Sampling for: 157504 |
| 484 Sampling for: 178890 |
| 484 Sampling for: 178891 |
| **Annual Reports & Annual Data/Product Reviews** |
| Annual Data/Product Reviews with attachments for 2003 – 2008 |
| Annual Reports with Attachments 2003 – 2008 (Part I of III) |
| Annual Reports with Attachments 2003 – 2008 (Part II of III) |
| Annual Reports with Attachments 2003 – 2008 (Part III of III) |
| **3rd Party Testing Documents** |

| |
|---|
| QRS Protocol |
| Updated recalled batches chart |
| Celsis documents |
| Gibraltar documents |
| Quantic documents |
| Deposition transcript of Liana Radtke with exhibits |
| **Pre-Recall Documents** |
| 2000 to 2008 Pre-recall MedWatch reports<br>2008 Pre-recall Product Complaint forms |
| 2008 Recall package |

## ATTACHMENT B

## Line Listing of Adverse Event Reports Received by the Manufacturer of Digitek®
## 2000 through 2003

Myocardial infarction, death
peripheral neuropathy, paresthesia
Pruritis
decreased digoxin level
Low digoxin level and atrial fibrillation
Low Digoxin level and atrial fibrillation
night sweats, hot flashes
Lack of effect
Weakness, drowsiness, disorientation
Upset stomach
nausea, diarrhea, constipation, peeling of finger nails & finger tips, fatigue, confusion, weakness of legs, pallor, shortness of breath & chest pain
shortness of breath, increased hear rate
breast tenderness, breast enlargement
blood glucose increased
blood glucose increased
increased postprandial blood sugars
dry mouth
swollen feet, increased blood pressure
increased sweating, tachycardia
CHF, cataract extraction, loss of appetite, visual disturbances, fatigue, weakness, anorexia & weight loss
abdominal distention
diarrhea, dizziness
blood bilirubin increased, esophageal spasm, hypertension, loose stools
cough
Pruritis, dermatitis, erythema, shortness of breath
atrial fibrillation
dermatitis, erythema multiforme
lack of effect, atrial fibrillation, premature ventricular contraction, premature atrial contraction
hair disorder
lighheadedness, headache, medicinal taste in mouth
loss of taste
lack of effect
drug effect decreased, nausea, weakness
generalized weakness, atrial fibrillation, feeling of being "in a semiconscious state", heart block
hives
generalized weakness
dizziness, fatigue, asthenia
decreased drug effect, atrial fibrillation
gynecomastia
in a clinical trial while on digoxin, experienced bowel obstruction (ileus), respiratory failure, rapid heart rate, deteriorated renal function, bleeding and digoxin toxicity
dizziness, fatigue, asthenia
lack of effect

## ATTACHMENT C

### Line Listing of Adverse Event Reports Received by the Manufacturer of Digitek® 2004 through 2008, up to but not Including the Recall

intermittent blurred vision
lack of effect
intermittent blurred vision
facial edema
nausea, dizziness
nausea, dizziness, intermittent stomach pain
hirsuitism
chest pain
alopecia
nausea, diarrhea
gynecomastia
sinus bradycardia, cardioactive drug level increased
blood alkaline phosphatase increased
orthostatic hypotension, hypotension, dizziness
atrial fibrillation, cardioversion, cardioactive drug level decreased
asthenia, chest pain, dyspnea, fatigue
vision blurred
rash, pruritis
cardiac failure congestive
diarrhea, fluid retention
thrombocytopenia
having problems
blood pressure increased
cardiac failure acute, cardiac failure congestive
tremor, gait abnormal
therapeutic agent toxicity, medication error
atrial fibrillation, lack of effect
cardiac arrhythmia, tachycardia
alopecia
drug ineffective, dysgusia, atrial fib
stomach discomfort
hyperaesthesia, burning sensation, erythema, cough, hoarseness
asthenia, fatigue, visual disturbance
cholecystitis, fatigue, asthenia, lethargy, malaise
amnesia, memory impairment, disorientation, dizziness, confusional state
headache, nausea, abdominal pain upper
patient concerned about possible medication error because of similar other pills, no adverse event
medication error
hypersensitivity, paresthesia, pruritis, feeling hot, erythema
GI discomfort, GI pain, vomiting, dizziness
patient reports 2 diff meds that look alike, no adverse event
overdose, xanthopsia, photophobia, optic nerve disorder, optic neuritis retrobulbar
bradycardia, syncope
subdural hematoma, International Normalized Ratio increased, coagulation time prolonged
tablets appear disintegrating, felt "compromised potency", drug effect decreased, cardioactive drug level decreased
heart rate increased, drug ineffective (heart racing)
jaundice